Immunex Corporation Docket No. 2813-L

properly numbered. In any event, applicants will refer to the claims as numbers 1-8 as indicated by the examiner.

The USPTO has rejected claims 1-8 under the doctrine of obviousness-type double patenting over U.S. Patent 5,843,423 in view of U.S. Patent No. 5,061,620. The USPTO argues that the invention claimed in the instant application is obvious over the invention claimed in the '423 patent. Applicants' respectfully disagree. As noted by the USPTO, the instant claims are directed to an in vitro composition and method while the claims in the '423 patent are directed to in vivo therapy in a patient. Clearly, the instantly claimed in vitro composition comprising the cell growth media and flt3-L is not an obvious variation of the in vivo method of the '423 patent. In fact, the components in the cell growth media are useful only for in vitro methods and are not suitable for administration to humans. No one of ordinary skill in the art would believe that the compositions claimed in the instant application could be used to stimulate hematopoetic stem cells in a patient because of the presence of the cell growth media.

In addition, the USPTO refers to "column 20, lines 21-33" of the Tsukamoto et al. patent. Applicants note for the record that no such column exists in that patent. Applicants examined the patent for the disclosure to support the USPTO's statement that "media formulations containing growth factors are suitable for hematopoietic cell expansion." No such disclosure could be found. In fact, the Tsukamoto et al patent refers to a *cell population* that is useful in reconstituting or repopulating cell types in vivo. Indeed, no mention of flt3-L is made in the patent.

In view of the fact that the instant claims are directed to compositions containing flt3-L and culture media, which media is not suitable for administration to humans, one of ordinary skill in the art would not have found the instant claims obvious. Applicants respectfully submit that no terminal disclaimer is necessary and request the withdrawal of the rejection.

In summary, applicants consider the pending claims to be in condition for allowance and respectfully request the issuance of a favorable action upon reconsideration.

Respectfully Submitted,

Stephen L. Malaska Attorney for Applicants Registration No. 32,655

Immunex Corporation Law Department 51 University Street Seattle, WA 98101

Telephone: (206) 587-0430

## **CERTIFICATE OF MAILING**

I hereby certify that the enclosed correspondence is being deposited via first class mail with the United States Postal Service on the date listed below, and addressed to Assistant Commissioner for Patents, Washington, D.C. 20231.

Date: - May 17,1999